

## REMARKS

### I. Introduction

The Examiner has withdrawn his previous rejections based on copending Application No. 20050137521 (10/944479) and copending Application No. 20050217679 (11/107618). Thus, the only remaining rejections are based on obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,793,664 ("the '664 patent") and claims 1-15 of U.S. Pat. No. 7,122,018 ("the '018 patent")

No amendments to the claims are made at this time.

Because Applicants submit this response within 2 months of the Final Office Action, Applicants respectfully request an Advisory Action, allowing the present claims.

### II. Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 9-15 and 17-33 are rejected by the Examiner on the grounds of nonstatutory obviousness-type double patenting over claims 1-15 of U.S. Pat. No. 7,122,018 ("the '018 patent") and claims 1-23 of U.S. Patent No. 6,793,664 ("the '664 patent").

#### U.S. Pat. No. 7,122,018 ("the '018 patent")

Applicants respectfully traverse this rejection because the Office action has not established a *prima facie* case of nonstatutory obviousness-type double patenting (hereinafter, "ODP").

The '018 patent is not an appropriate obviousness-type double patenting reference. The '018 patent was filed on December 23, 2004 and claims priority to at least the present application (10/615,546). The present application (10/615,546) was filed on July 8, 2003, claiming priority to a provisional application of July 9, 2002.

Therefore, the '018 patent is a continuation of the present application (10/615,546). Said another way, the present application (10/615,546) is the parent application of the '018 patent.

The term of the '018 patent could not and would not be "extended" by the issuance of the present application. This is because the present application was filed prior to the filing of the '018 patent and the '018 is a continuation of the present application (10/615,546). Since the issuance of the present application would not result in the extension of the term of the '018 patent, the Examiner has not established a prima facie case of ODP.

A ODP rejection was not designed for the present situation, wherein the Examiner has rejected the parent application (10/615,546) on the basis of its continuation ('018 patent). Applicants respectfully request that the ODP rejection based on the '018 patent be withdrawn.

**U.S. Patent No. 6,793,664 ("the '664 patent")**

First, it is noted that the '644 rejection should not be the basis of a ODP rejection because both the inventorship and ownership between the present application and the '644 patent are different. Therefore, the Applicants respond to this rejection as if it is a rejection under 35 U.S.C. § 103.

Despite the labeling of the rejection, it is maintained that the '644 patent does not teach or suggest the presently claimed invention. The limitation of applying a wound healing agent to damaged tissue is recited in all the independent claims (i.e. claims 9, 10, 11, 12, 13, 14, and 15) of the present application. In contrast, the '664 patent teaches

away from the use of a wound healing agent. Thus, the '664 patent does not suggest the claims of the present application.

The Examiner states that the ODP rejection is proper because "[o]ne would have been motivated to do this since nitric oxide and the wound healing agents promote the healing of the wound." (Final Office Action, p. 3, citing *KSR*). In light of the fact that the ODP rejection is read as a 35 U.S.C. § 103 rejection, Applicants maintain that the '644 patent teaches away from using a wound healing agent. Col. 1, lines 17-57 of the specification of the '644 patent states several distinct problems with use traditional agents on tissue. The agents that the '644 patent teaches against are taught and claimed in the present application as "wound healing agents." The full passage of the '644 is repeated below:

The treatment of infected surface or subsurface lesions in patients has typically involved the topical or systemic administration of anti-infective agents to a patient. Antibiotics are one such class of anti-infective agents that are commonly used to treat an infected abscess, lesion, wound, or the like. Unfortunately, an increasingly number of infective agents such as bacteria have become resistant to conventional antibiotic therapy. Indeed, the increased use of antibiotics by the medical community has led to a commensurate increase in resistant strains of bacteria that do not respond to traditional or even newly developed anti-bacterial agents. Even when new anti-infective agents are developed, these agents are extremely expensive and available only to a limited patient population.

Another problem with conventional anti-infective agents is that some patients are allergic to the very compounds necessary to their treat their infection. For these patients, only few drugs might be available to treat the infection. If the patient is infected with a strain of bacteria that does not respond well to substitute therapies, the patient's life can be in danger.

A separate problem related to conventional treatment of surface or subsurface infections is that the infective agent interferes with the circulation of blood within the infected region. It is sometimes the case that the infective agent causes constriction of the capillaries or other small blood vessels in the infected region which reduces bloodflow. When bloodflow is reduced, a lower level of anti-infective agent can be delivered to the infected region. In addition, the infection can take a much longer time to heal when bloodflow is restricted to the infected area. This increases the total amount of drug that must be administered to the patient, thereby increasing the cost of using such drugs. Topical agents may sometimes be applied over the infected region. However, topical anti-infective agents do not penetrate deep within the skin where a significant portion of the bacteria often reside. Topical treatments of anti-infective agents are often less effective at eliminating infection than systemic administration (i.e., oral administration) of an anti-infective pharmaceutical.

Col. 1, lines 17-57 of the specification of the '644 patent.

Thus, it is maintained that these 3 long paragraphs teach away from the use of the traditional wound healing agents on tissue, as presently claimed. One of skill in the art reading the '644 patent would not be motivated to apply both gNO and a wound healing agent to tissue, as presently claimed.

Thus, Applicants respectfully request withdrawal of the rejection based on the '644 patent.

### III. Conclusion

Applicants respectfully request that the nonstatutory obviousness-type double patenting rejections of claims 9-15 and 17-33 be withdrawn and a Notice of Allowance be issued for all pending claims.

If the undersigned can be of any assistance to the Patent Office, a telephone call is respectfully requested. If any fees are required by this filing, the Commissioner is authorized to charge Sidley Austin LLP's Deposit Account # 50-1597.

Respectfully Submitted

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